K052249

DEC 7 2005

510(k) SUMMARY

Submitter's Name:	RespCare Inc.
Submitter's Address:	6601 Lyons Road, Suites B1-B4 Coconut Creek, Fl 33073, USA
Telephone Number:	(561) 208-3778
Fax Number:	(954) 727-8479
Contact Person:	Frank Pelc
Date:	August 17, 2005
Proprietary Name:	Utopia
Common/Usual Name:	Face Mask
Classification:	Class II, CFR 868.5905, BZD
Classification Name:	Accessory to Noncontinuous Ventilator
Predicate Devices:	K030822 – Hans Rudolph 7600 Vmask K040506 – Fisher & Paykel HC431 K002465 – Respironics PerformaTrak

Device Description
The Utopia is a patient interface accessory to a positive pressure ventilator intended for treatment of respiratory insufficiencies and obstructive sleep apnea. The device delivers positive airway pressure from a CPAP or bi-level device to the patient's oral and nasal passages. Connection to the ventilator device is made by a standard 22 mm fitting. The mask is held in place on the face by a forehead pad and headgear worn around the head. The device includes exhalation port, anti-asphyxia valve, and oxygen entrainment port features.

Comparison to Predicate Devices
The Utopia is essentially similar to the legally marketed predicate interfaces listed above in function, intended use, materials, and features.

Both the proposed device and the predicates are intended to be used as a patient interface for currently-marketed CPAP or Bi-Level positive-pressure ventilation devices for treatment of respiratory insufficiencies and obstructive sleep apnea. The Utopia is offered in single use and multiple patient, multiple use versions. Predicate examples are offered for both single and multiple use for comparison.

Like the predicate masks, the Utopia delivers non-invasive positive airway pressure from a CPAP or bi-level flow generator to the patient's oral and nasal passages. The Utopia provides a seal against the face as it is held in place with a headgear worn around the head similar to the predicates.

Exhalation ports are provided on the mask shell. An anti-asphyxia valve is provided as a safety feature in case of low pressure delivery from the ventilator device. Accessory ports for oxygen entrainment are provided. Each of these features is comparable to predicates mentioned above. Materials used in the Utopia are comparable to the predicates as well.

Substantial Equivalence

The Utopia is equivalent to the predicate devices in intended use, environment of use, patient population, and frequency of use. Its basic method of operation and design is also equivalent to the predicates, as described in the comparison above. Materials information and functional testing relative to the intended use of the Utopia show that it is as safe and effective as the predicate devices.

As such, it is RespCare's conclusion that the Utopia is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 2005

Mr. Frank Pelc
Director, Regulatory Affairs and Quality Compliance
Respcare, Incorporated
6601 Lyons Road, Suites B1-B4
Coconut Creek, Florida 33073

Re: K052249
Trade/Device Name: Utopia
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: November 3, 2005
Received: November 4, 2005

Dear Mr. Pelc:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

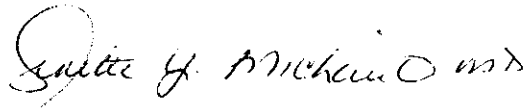
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: *Utopia*

Indications for Use:
The Utopia is intended for use by adults (> 30 kg) as a patient interface for currently-marketed CPAP or Bi-Level positive-pressure ventilation devices for treatment of respiratory insufficiencies and obstructive sleep apnea.

(Applies to the standard version):
For homecare applications, the Utopia may be reused multiple times by a single patient. For institutional applications (i.e. hospital or other clinical settings), this interface may be reused multiple times by multiple patients.

(Applies to the Disposable version):
The Utopia Disposable is a single patient, single use interface.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

W. Maly for A. Graham

...sion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(K) Number: K052249